

Volume VI Issue 47
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POSTSCRIPTS

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Official publication of the American Medical Writers Association Pacific Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

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Chapter website: <http://www.amwa-pacsw.org>
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COVER: On highway from Arizona to Denver. Picture kindly provided by Megan Garlapow. 2016.

From the President's Desk

First of all, thanks to everyone from our chapter who participated in the AMWA national meeting (now known as the Medical Writing and Communication Conference) from October 5 through 8 in Denver. Our annual chapter dinner was a huge success, thanks especially to the expert event planning by Donna Simcoe and Elise Sudbeck. You will see how much fun it was from all the smiling faces in the photo montage in this issue. As you'll also see, our members were inspired to write extensively about their experiences at the conference, so you'll need to set aside an evening or two to catch up with all the reportage.

This issue also covers presentations from the 2016 Medical Writers' Toolbox Symposium, held again in Thousand Oaks in September and graciously hosted by Amgen. We are very grateful to Amgen for their support, and to all the speakers and volunteers for their contributions. Maggie Norris came down from the north to show us how to get the most out of Microsoft Word, Donna Simcoe and Ajay Malik surveyed the latest in document management tools, and Julie Gegner provided a fascinating introduction to the booming field of health economics and outcomes research. As always, this was a great educational and networking opportunity for our chapter.

Our mentorship webinar for mentors and mentees is now scheduled for December 1, and there is still time if you would like to get training to participate in either role. Please contact me as soon as possible at president@amwa-pacsw.org, and if you can't make this event, remember that we are hoping to schedule a presentation about mentoring next year for the general membership.

Meanwhile, the holidays are almost upon us, and we are hoping to organize a celebration for early January. We'll keep you posted as our plans firm up, and if you have any fun ideas for a venue or activity (hopefully located in Orange County or Los Angeles) please do contact me at the email shown above. And, as always, if you would like to sponsor a smaller get-together in your neighborhood, such as a happy hour or brunch, be sure to let us know how we can help you. Happy Thanksgiving!

Susan

Susan Vintilla-Friedman, MWC
President, AMWA Pacific Southwest Chapter



How we Deliver and Consume Research and Ideas: At Meetings, in Journals, and Back Again at Meetings

The ways in which scientists (and philosophers) have communicated their ideas, hypotheses, and results to their peers and to the public have changed and then changed back over the last 300 years. In Darwin's days, presenting at meetings organized by learned societies (eg, Royal Society of London) was the preferred way to share new research, wacky hypotheses, and interesting ideas; heated debates were the peer review system of the day. Only months later, those presentations would finally appear as narratives in the society's proceedings or memoirs.

Then, in the beginning of the 19th century, with the introduction of cheaper and more efficient printing presses and increasingly reliable transport system (not to mention commercial interests), the number of journals exploded from about 100 to 10,000 by the close of the century. This dramatic surge in the number of journals offered scientists more choices in where to publish, but it also led to a push towards specialized journals with compartmentalized audiences limiting cross-fertilization of ideas. Access to information has also been affected—since the discovery of the DNA double helix, commercially backed journals have slowly erected paywalls limiting (free) public access to research articles.

But with the public's "taxpayer revolt" and the demand for access to publicly funded research, the mechanics of how and where scientists report their findings is changing yet again. Publishing in open access journals is a positive step. Last month, the European Union started posting all clinical data (from clinical study reports) from the EMA-approved medicines online. Also, major clinical meetings and forums are once again becoming more important in how research and ideas are delivered to peers and to the public. These days, every pharmaceutical company has a medical disclosure plan to share results of clinical studies. Some meetings, such as the annual American Society of Clinical Oncology meeting, have cult-like followings among patient advocacy groups and Wall Street.

Meanwhile, closer to home, AMWA has similarly evolved with the times. This year was the first time that AMWA's annual meeting was held in Denver, Colorado, under the banner "Medical Writing & Communication Conference." This AMWA meeting had opportunities for learning, networking and exploring to satisfy the professional development needs of *all* medical communicators, just as the sharing of ideas happened in the 18th century Royal Society's meetings!

As with the *Proceedings of Royal Society*, the *AMWA Journal* is expected to cover the Denver meeting in much detail in the upcoming Spring 2017 issue. However, we at *Postscripts* are fortunate to be able to offer you a first look. In this issue of

Postscripts, five AMWA members who were at the conference share their experiences: Megan Garlapow, Eileen Hoshino, and Kristina Jong describe their experiences as first-time attendees (see pages 161-162, and 165). Social media added another dimension to the meeting experience. Rochelle Mikkelsen, who live-tweeted the conference, writes that her regular tweeting increased her visibility and enhanced her connections with other AMWA members (read her meeting report on page 163-164).

For many AMWA members, medical writing as a career means a *freelance* career—one that lets them set their own hours but that also requires investment in managing the business side of writing. Gail Flores summarizes the key takeaways from the freelance-themed sessions at the AMWA conference on page 166.

This meeting was also a time to meet old friends and to meet new ones at dinner parties, and to explore Denver. Susan Vintilla-Friedman took the opportunity to walk to the Denver Art Museum, where she discovered artists' renditions of chairs and concepts about chairs (see backpage).

One difference in the meetings held in today's hyper-connected culture compared to that of the 18th-century Royal Society era is the ubiquity of social media: Twitter, Facebook, LinkedIn, and blogs. Few medical writers are apparently active on Twitter, but there was a core group whose posts with the hashtag #AMWA2016 allowed the rest of us to get a flavor of this year's AMWA conference. A curated list of tweets with hashtag #AMWA2016 appears on page 167.

Brian Bass, the Past President of AMWA, summed up the experiences from this meeting in a closing tweet: "#AMWA2016 best medical writing & communication conference ever! So good seeing friends. Great knowledge exchange! Can't wait for #AMWA2017."

Acknowledgement

The author thanks Clare Prendergast, MA, for editing this article and providing helpful suggestions.

Notes and Sources:

- Shuttleworth S, Charnley B. Science periodicals in the nineteenth and twenty-first centuries. *Notes Rec* (2016); 70: 297-304. DOI: 10.1098/rsnr.2016.0026.
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Praxis

By Hope J Lafferty, AM, ELS, AMWA Southwest Chapter Member

Tabula Plenus: The Power of Unlearning

I recently attended an Educators' Symposium¹ for high school teachers who run creative writing programs. I'm not planning to shift my focus to school-aged children, but I spend so much time in the andragogic space, I wanted to swim in the waters of pedagogy for a while to see how those methods could apply to my work.

If I'm stumping you with the terms, pedagogy is education; andragogy is adult education.² We don't think about how we learn as we age, because we still read, write, and calculate based on what we learned in school. But when we want to learn a new topic or skill, we come in with years of knowledge, habits, and even fears that get in the way of our learning.

I hadn't thought about this distinction myself until I studied with Catherine Mattiske about 15 years ago. My dog-eared copy of her book *Train for Results* has helped me develop both training programs and all kinds of writing projects. Catherine taught me that adults are not blank slates that we fill with information, like we do with young people. Before anything new will stick, adults have to unlearn some of what we already know to make room for the new information. So I was surprised by how many of the pedagogic techniques that we discussed in the Educators' Symposium could apply to my clients. In fact, some methods came from my own writing playbook, like writing prompts, timed writing, and reading aloud.

It hit me that not only could I bring contemporary writing conventions to my clients (ie, filling them with

information), but I could also help them break the less-than-effective writing habits that were holding them back (ie, make room for new information).

The upshot of this insight spawned my new program, The Writing Clinic, which was offered at this year's AMWA annual conference in Denver. This program moves beyond the instructional content of my other programs and allows participants to actually practice writing. And not writing for a specific project. Writing as writing. Imagine that.

Like the mystics say, you can't get good at writing unless you write. If you don't already, set up your own writing clinic and spend some time just writing for the sake of writing. Have fun!

¹I thank the good people at The Porch Writers Collective in Nashville for letting me participate.

²Coined by American educator Malcolm Knowles in the 1970s.



HOPE J LAFFERTY, AM, ELS, is Chief Communicator at Hope Lafferty Communications and Co-Founder of the Scientific Writing Academy. She has written recreationally since she was 9, got her first proofreading gig at 19, holds a masters in group work from the University of Chicago, and became a certified trainer with the Association for Talent Development. She serves as AMWA 2017 Annual Conference Chair and President-Elect of the Board of Editors in the Life Sciences (BELS). Whenever she's not writing or producing something for herself or others, she unwinds behind the wheel with her musician husband and their dog. Connect with Hope at hope@hopelafferty.com.



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Communication
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Trends and Opportunities for Medical Communicators

Banned Words – 2016 Edition

By Rebecca J Anderson, PhD, AMWA Pacific Southwest Chapter Member

In case you missed it, Lake Superior State University has published its 2016 list of banned words. Each year, the gurus at LSSU sift through hundreds of nominations from word-watchers all over the world and pick the words and phrases that they think should be banished from the Queen's English because of "mis-use, over-use, or general uselessness."

In the service of good medical communications, let me highlight items on the 2016 list. You may want to consider redacting them from your dictionary and vocabulary.

Problematic – The Urban Dictionary calls this a "corporate-academic weasel word." Somewhere along the way, "problematic" became a trendy alternative to "problem," especially when speakers wanted to soften the impact of something that didn't quite reach the level of a "problem." Why not call such things inconvenient or undesirable, and preserve "problem" for actual problems, like mosquitoes?

Stakeholder – This word used to be ok (ie, referring to someone who really has a stake in something). But now it's over-used and describes almost anyone. The expanded version often pairs "stakeholder" with "engagement," but stakeholders are already engaged. Those who are not engaged are not stakeholders. Duh!

Secret sauce – We can blame the fast food industry for promulgating this one. In its current, widespread use, "secret sauce" has become a metaphor for business success. Interestingly, in most cases, when business types mention "secret sauce," they go on to explain the "secret" in exhausting detail. My grandmother's marinara is a secret she'll take to her grave. Corporate secret sauce is neither a secret nor a sauce.

Price point – An example (like so many others) of using two words when one will do. It's just a "price."

Break the internet – Hyperbole is always a bad strategy in any type of writing, but really? Videos, Facebook posts, and tweets go viral (a word banned by LSSU in 2011)—that's bad enough. People like

Edward Snowden and the Russians routinely **break into** the internet, but when was the last time your internet actually **broke**?

Walk it back – Perhaps this was meant to be a milder, gentler, and slower version of back-pedaling. In our current political season, candidates make outrageous statements every day, and then they "walk it back" the very next day. Politics means never having to say you're sorry, and walking takes less energy than pedaling. LSSU's reasons for banishing this one should be obvious.

Vape – Used to describe the act of "smoking" e-cigarettes, which emit vapor instead of smoke. The experts at Lake Superior State want this word to go up in smoke.

Giving me life – Another hyperbole—and a nonsensical one. Biologically, of course, our parents give us life. But this term now refers to anything that may be exciting or makes you laugh. "Giving life" is an extraordinarily high bar for a Saturday night sitcom.

Physicality – During the Olympics, "physicality" was especially popular with sportscasters and sports writers. No one knows what it means, but it sounds good and makes the commentators appear more credible. Let's hope they expand their vocabulary to include more descriptive words before the Korean games. I'll even lend them my Thesaurus.

The complete LSSU list for 2016 can be found at:
<http://www.lssu.edu/banished/>

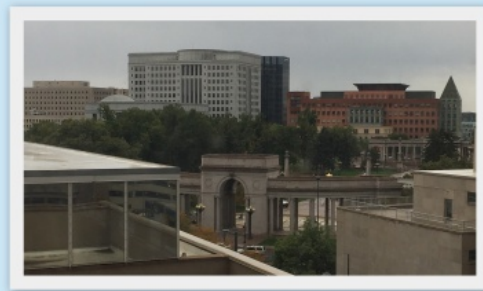
REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a PhD in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.



BIGLY!

Pictures From the AMWA Conference in Denver

By Gail Flores, PhD, AMWA Pacific Southwest Chapter Member



2016
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Trends and Opportunities for Medical Communicators



My First AMWA Conference: What good is sitting alone in your room? Come hear the music play!

By Megan Garlapow, PhD, AMWA Pacific Southwest Chapter Member

The 2016 AMWA Medical Writing and Communications Conference in Denver, Colorado, was my first AMWA conference. In many ways, the experience felt like coming home, and not just because I grew up in Denver. The experience also felt like home in that I found myself surrounded by a large group of supportive, skilled, and enthusiastic people who were more than happy to foster meaningful connections and engage in important conversations.

I began my career in medical writing and communications primarily through serendipity: After moving to Arizona in 2015 for a postdoctoral research position, I quickly realized that academia was no longer the right fit for me. After speaking with anyone who was willing to speak, I was introduced to Kathy Boltz, Ph.D., a freelance medical writer, and member of the AMWA Pacific Southwest Chapter (and until recently the liaison for the Chapter's Arizona satellite group), who also happened to live nearby. Prior to my first conversation with Kathy over coffee, I had no idea what medical writing was. It was that first conversation with Kathy that ultimately resulted in my choosing the path of becoming a freelance medical writer. With Kathy's encouragement, and her offer to share a hotel room at the AMWA conference, I headed to Denver.

Like many other medical writers, the idea of striking up a conversation with someone in a room full of strangers makes my stomach want to do somersaults, but I was prepared, the first line of "Cabaret" ringing through my head: "What good is sitting alone in your room?" There's nothing like channeling Liza Minnelli playing Sally Bowles to help me overcome my tendencies toward introversion. With that, on Wednesday, I took my plate of fish tacos at the hotel bar and asked a table of three medical writers if I could sit with them. I admit to recognizing Lori Alexander's face from AMWA Engage and from other AMWA communications. It turns out I had no need to worry! People were welcoming.

I headed into Thursday with excitement, first attending the "New to AMWA and Medical Communication Session" where I met two AMWA members with whom I shared lunch. I would be untrue to my hometown if I didn't put in a plug for pork green chili. The Alvarez Award Address by Roxanne Khamsi left me feeling inspired and self-

reflective. For example, I need to be aware of my audience when I explain that I have experience writing on hematological malignancies when I could just as easily say, "blood cancers."

The sessions I attended primarily focused on the art and strategy of freelancing, allowing me to glean useful insights from my more seasoned freelancing colleagues. And I had the opportunity to meet in person some people with whom I have interacted electronically. I always enjoy meeting people face-to-face, especially when we have worked together on projects! The dine-around afforded me the opportunity to get to know even more medical writers, with one conversation extending both beyond dinner and beyond the subject of medical writing. This sort of a connection would not have happened if I had sat alone in my room. Indeed, Sally Bowles is correct: "Come hear the music play!"

As the conference ended, I felt inspired and motivated, having forged connections and ruminated on ideas that I would not have otherwise had.

MEGAN GARLAPOW, PhD, is a freelance medical writer, who has written about a wide range of medical and scientific topics and supported competitive intelligence research. Her projects have included promotional materials; reporting remotely and on-site for medical conferences; writing for medical news organizations; developing posters, abstracts, and slide-decks for national conferences; and developing peer-reviewed manuscripts. Before her career as a medical writer, she worked in a biopsychology lab examining social factors affecting breast cancer patients; and in a neurogenetics lab examining the circadian factors affecting nicotine addiction in a mouse model. Megan earned her PhD in Genetics from North Carolina State University, where she studied the regulation of feeding in fruit flies using quantitative and physiological genetics methods—the work she continued in her postdoctoral research at Arizona State University, examining the environmental and genetic factors affecting body weight in fruit flies. She can be reached at megan.garlapow@gmail.com. Her website is megangarlapow.com.



Denver or Bust!

By Eileen Lai-Hoshino, MSc, MBA, MPH, Principal, Medco Writing and Communications, and Outreach Coordinator, AMWA Pacific Southwest Chapter Member

For a first-time attendee, the national 2016 AMWA conference held in Denver earlier this month did not disappoint. What was most impressive to me was the sheer number of workshops offered, ranging from basic grammar and paragraph building to those focused on specific types of regulatory writing. Likewise, the open sessions ranged in topics from editing and quality control to how to use social media effectively. I was at times, overwhelmed by the numerous choices of open sessions covering topics that spanned nearly all aspects of medical writing and its practice as a freelance business; but as a new medical writer, I appreciated the variety of opportunities to expand my horizons within the vast field of medical writing.

One of my goals in attending the conference was to understand the types of medical writing specializations. Given my background as a clinician, several areas, such as, regulatory and health economics are of particular interest to me, so I attended several regulatory science-based workshops and sessions, including those on writing of the Academy of Managed Care Pharmacy (AMCP) dossiers and hospital value-based purchasing (VBP). Both AMCP and VBP documents are key to the decisions controlling market access to medicines and healthcare in our private healthcare insurance-based system.

The majority of the workshops and sessions that I attended were practical and informative, and I was able to apply a few things to my current projects. I was particularly impressed with the workshop, "Writing Clinical Evaluation Reports for Medical Devices," led by Felicia Cochran. While I had no prior experience writing clinical evaluation reports, what I learned about this type of document writing appealed to my clinical safety background and interest in medical devices. Ms. Cochran presented a concise but thorough presentation, keeping the students engaged with interactive exercises and questions.

I also felt inspired by a session that catered to freelancers: "\$200 (or More) an Hour, Yes, You Can Do It." The panel speakers in this session, Debra Gordon, Michelle Dalton, and Scott Kober, were all very experienced writers with successful freelance businesses. The perspectives and advice they offered was heartening to a new writer, and I

appreciated the congenial session environment in which everyone generously offered additional tips and encouragement.

In general, I have found my fellow AMWA medical writers to be supportive and gracious professionals, something I have not often always experienced in other professions. My transition from a hands-on, clinical career to one where I spend most of my time on the computer keyboard, has taken some adjustment for me. But now, after my first AMWA conference, I come away feeling more confident in the new path that I am pursuing and energized about being part of the AMWA "village."

Eileen Cecilia Lai-Hoshino, MSc, MBA, MPH is an experienced medical professional in science/medical writing, marketing, and communications. Her specializations, include continuing medical education, health economics and outcomes research, regulatory writing, and health and wellness marketing. Previously, she worked in the clinical environment as a licensed medical professional (PA-C); and as a healthcare management consultant with projects including strategic planning, marketing, performance management, and training design in the healthcare industry. Eileen has a master's degree in anesthesiology and critical care medicine from Emory University, Atlanta, and she earned double masters (in business administration and in public health) from Columbia University, New York. Eileen can be reached at eileen.hoshino@gmail.com or through her website www.medcowriting.com.



#AMWA2016: Cronuts, Grammar, and the Medical Writing Connection

By Rochelle Mikkelsen, PhD, Medical Writer & Consultant, Whitsell Innovations, Inc, Chapel Hill, NC, and Member, AMWA Carolinas Chapter

I knew I was at the #AMWA2016 Medical Writing & Communication Conference in Denver the minute I sat down at the opening session and spied a bag beside the next table, adorned with a button (the kind you were awarded in elementary school for being an All Star Reader!, or the type handed out by presidential election campaigns [too soon?]). The button read: “I’m silently correcting your grammar.” I was finally with my linguistic-loving, science-crazy, medical writing tribe.

The 4-day conference was bookended by powerful talks: Roxanne Khamsi, gave this year’s Alvarez Award address on the second day of the meeting, “What to Leave Out, What to Keep In: Inclusion and Exclusion Criteria for Medical Writing.” And, on the last day of the meeting, Kevin Pho, MD delivered the McGovern Award address: “Connect and Be Heard: Make a Difference in Health Care with Social Media.”

Donuts and Cronuts

Roxanne Khamsi, Chief News Editor at *Nature Medicine*, reminded us of the power of words. She recounted a story of a patient with a moderate heart condition, who heard her doctor say to a colleague that she had TS. Unfortunately, the patient interpreted TS as “terminal syndrome.” Within hours, anxiety over the doctor’s unexplained diagnosis led to the patient’s death, despite the nonserious nature of her complication. Ms. Khamsi further explained how big words and jargon can fall short in science communications: ‘tumor progression’ can easily be interpreted as a good thing! She used donuts and croissants as a genius analogy to represent distinct reading audiences, typical of past hardcopy formats. Online audiences today are more like cronuts, a delicious mix of diverse backgrounds. We had to stare at an 8-foot cronut projection while, teasingly, Roxanne held up a REAL cronut behind the podium. It would have been a perfect time for a loaves-and-fishes AMWA cronut miracle, to help us concentrate

on everything we were about to learn. *Really, that was my only complaint during the whole conference.*

Word and Acrobat Hacks

In the first open session I attended, tech-heads Robin Whitsell and Ann Winter-Vann, PhD expounded on Word and Acrobat hacks. Did you know that you can automatically replace those pesky multiple spaces with a tab? Just a little {3,50} here and a ^t there, and you’re on your way. The speakers suggested the app If This Then That (IFTTT) to organize and expedite social media posts. Pro tip: iPads can serve as handy double monitors with duetdisplay.com. This presentation was a microcosm of #AMWA2016: lots of sharp information we can all put to use.

Early Birds Get the Seats

Several sessions were standing-room only, like Peggy Boe’s nuts-and-bolts QC talk. Contrary to conventional wisdom, Ms. Boe reminded that the use of passive voice isn’t off-limits if you want to emphasize the action and not who did it; the use of passive voice is common in regulatory writing. We learned that the Methods section of a clinical study report (CSR) can be written and QC’d before clinical data are available (pre-database lock), to save time on the backend. And long live the Oxford comma!

Joanna Harris and Kimberly Jochman, PhD preached consistency in their regulatory writing session (patients either survived or died, but should not flip flop, unless they’re named Lazarus). Summarizing results precisely in the text can interfere with readability—use data tables for maximum precision. They advised placing the most important information at the beginning of the paragraph...not here, at the end of the paragraph.

The CORE Reference session was packed with writers seeking to understand the new CSR authoring tool designed to standardize ICH E3-based reporting. CORE, an acronym for “Clarity and Openness in Reporting: E3-based,” is a user manual to help medical writers create CSRs that are compliant with regulatory rules and guidelines. For example, the CORE structure includes a section that summarizes key changes in the conduct of a study and differences between the protocol and statistical analysis plan. Following CORE reference helps plan for redaction of CSR sections to protect patient privacy or company’s privileged information when clinical trial results are made public, as is now required by European regulatory bodies. Aaron Bernstein, PhD, a speaker and one of co-authors of



Rochelle
@rochelleonearth



Following

Winston Churchill: 'Broadly speaking, the short words are the best, and the old words best of all.' Awesome keynote by @rkhamshi
[#AMWA2016](#)

LIKES
3



3:21 PM - 6 Oct 2016

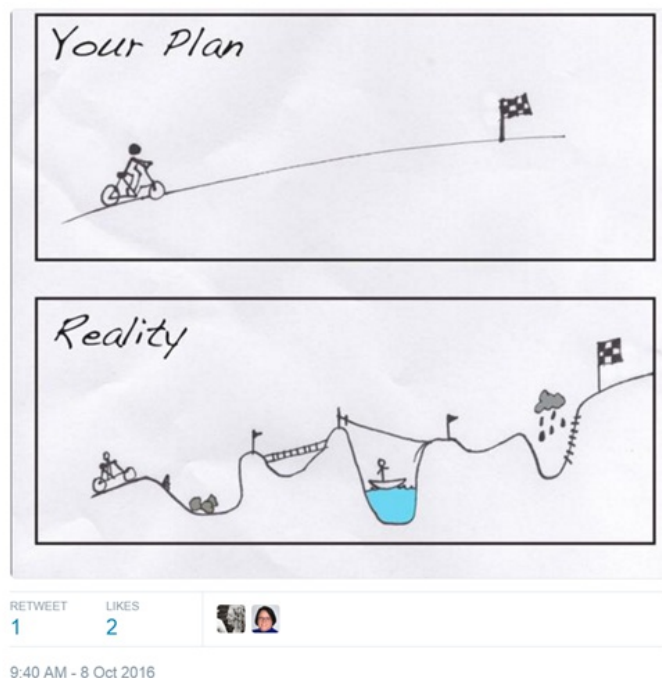
CORE, closed with this comment on the adoption of CORE: “It’s a matter of the path being made by people walking on it.” The CORE reference is available at www.core-reference.org.



Rochelle
@rochelleonearth



Rendering, compiling, components, trackers: great discussion on the realities of publishing in Kelly Kilibarda's session. [#AMWA2016](#)



Published Document Gift-Wrapping

Kelly Kilibarda, PhD led an energized discussion on the realities of publishing, which is rarely a smooth process. Rendering, compiling, components, and trackers were defined so writers could talk shop with publishers. Early meetings, formatting checks, and bookmarking and linking TLFs upfront were suggested to facilitate timelines. The final published document was likened to a cellophane-wrapped gift basket. In the end, you might notice a packet of tea in what is supposed to be a bath-themed gift, but it’s rarely worth it to undo the whole package to make a small fix.

The Power of Social Media

Kevin Pho, MD emphasized the power of social media to effect real change in his talk on the final day of [#AMWA2016](#). Just as Ms. Khamsi pointed to the power of words, Dr. Pho used anti-vaccine advocacy as an example of how social media can influence public opinion in spite of scientific data contrary to claims made in tweets or blogs. For example, every time there is an anti-vax uproar in the media, it sets back vaccine rates by three years.

As medical professionals, we need to do our part to set the record straight. As writers, we need to remember that “stories are just data with a soul,” said best by Brene Brown. Kevin Pho quoted Leon C. Megginson: “It is not the strongest of the species that survives, nor the most intelligent, but the one most adaptable to change.” This is truly a sentiment to be applied time after time in life and career, and an inspiration to get creative and bold in our social media outreach.



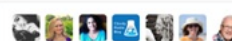
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.@BreneBrown: 'Stories are just data with a soul' - we cannot lose the medical PR battle online. @kevinmd [#AMWA2016](#)

RETWEETS
4

LIKES
5



8:25 AM - 8 Oct 2016



4



5



At this meeting, I took the opportunity to live-tweet the conference ([@rochelleonearth](#)), which increased my visibility, enhanced my connection with other attendees, and led to an invitation to share my experience with *Postscripts* readers. I even picked up a troll on my vaccine post, a social media rite of passage. [#AMWA2016](#) provided homerun advice and strategies to improve writing and business alike, but it was perhaps most valuable serving as a home base to medical writers, who are strengthened by their connections with each other. Thank you AMWA for a great meeting and the awesome name tag ribbons!

ROCHELLE MIKKELSEN, PhD is a medical writer and consultant for Whitsell Innovations, Inc in Chapel Hill, North Carolina. Prior to medical writing, Dr. Mikkelsen was a GLP study director specializing in pharmaceutical interactions with the immune system. She holds a PhD in immunology from North Carolina State University. When she is not writing, she enjoys painting, running, and avoiding bears in the Appalachian mountains. She can be reached at rochelle.mikkelsen@whitsellinnovations.com.



My Journey to the Center of the AMWA Universe

By Kristina Jong, MD, AMWA Pacific Southwest Chapter Member

Although I have been an AMWA member for two years, I have procrastinated about going to the AMWA National Conference or the local chapter (Pacific Southwest Chapter) meetings. I didn't think I would belong and just kept telling myself "*wait until next year.*" This September, I finally dragged myself to my first chapter meeting held at Amgen in Thousand Oaks. There I saw only friendly, smiling faces and everyone was happy to share their own experiences. This was just the kind of networking and first-hand knowledge that I needed. I made up my mind—I simply had to go to the national conference, which was renamed this year as "2016 Medical Writing & Communication Conference." This was a 4-day conference held in Denver from October 5th to October 8th.

Enter Denver.

On the morning of my first day of the conference I met up with Lynn Griffin, PhD, a fellow Pacific Southwest Chapter member, and we headed off to the "New to AMWA and Medical Communication" session. I expected a small gathering of 20 or so people, but was surprised to see a room packed with nearly 300 people. Cynthia Kryder, co-author of *The Accidental Medical Writer* series, led the session and began with an overview, the "31 Flavors of Medical Writing." She went on to explain how to get the most out of the conference and AMWA. "Must do" events for newbies and sessions to explore the different areas of medical writing were suggested. There was a contest to see who could work their smartphones fast enough to find facts about AMWA and its offerings from the AMWA website. Apparently my fingers were not nimble enough. But Lynn's were and she came away with a writing guide book.

Next up was the Alvarez Award Address, "What to Leave out, What to Keep In: Inclusion and Exclusion criteria for Medical Writing," presented by Roxanne Khamsi, Chief News Editor of *Nature Medicine*. She gave a humorous but thought-provoking lecture about the evils of jargon and why we should avoid using it. She recounted the sad story of "Mrs. S.," a middle-aged woman with a well-controlled heart condition who died suddenly from jargon. She was doing well after completing a weekly treatment for her heart condition when she overheard an esteemed physician casually remark to a group of trainees, "This woman has TS." Mrs. S. was convinced TS referred to "terminal situation." She became extremely agitated and within minutes began to experience heart failure. She was admitted to the hospital that afternoon and died shortly thereafter. As a physician, I found the story extremely moving.

I spent the rest of conference taking in a diverse set of sessions including "Best Practices in Writing Test Items" and "QC Review of Safety Narratives." "\$200 (or More) an hour? Yes, You Can do it" seemed to be the most popular, with several attendees pulling up extra chairs and filling in the aisles.

I even attended one of the Speed Networking sessions, which was a fun way to meet 12 people in an hour—and great opportunity for distributing all those business cards!

On Friday (the 3rd day of the conference), I ended the day with hearty and generous Italian fare and good conversation at our Chapter dinner at Maggiano's Little Italy restaurant in downtown Denver. Every shade of medical writing spectrum was represented by writers at my table, and included our chapter President, Susan Vintilla-Friedman, a freelance writer, a full-time employed writer, a full-time employed editor, and a new-to-the-field writer enrolled in the Medical Writing certificate program at University of California San Diego.

The last conference session I attended, "Closing the Deal: Getting that Freelance Project," was perhaps the most entertaining. Alisa Bonsignore, Director for the Society for Technical Communications, was a polished and witty presenter who was full of practical tips (including an expiration date on your proposals, unless you want a client to return months later expecting you to be available) backed with humorous personal anecdotes.

Before packing my bags to go to this year's conference, I thought that there was no way I would journey all the way to Orlando for next year's. But now I'm planning on making the cross-country trip for the 2017 Medical Writing & Communication Conference. There, look for me wearing the Mickey Mouse ears in the first row!

KRISTINA JONG, MD, is a board-certified radiologist who specializes in breast cancer imaging. She has an appointment as Adjunct Clinical Instructor at Stanford University School of Medicine. She is also a consultant to medical device companies and has worked on regulatory documents and physician education materials. She can be reached at kristinajong@gmail.com.

Successful Freelancers Share Their Wisdom at #AWMA2016

By **Gail Flores, PhD**, Encore Biomedical Communications,
and AMWA Pacific Southwest Chapter Member

I attended four open sessions in Denver presented by successful freelance medical writers: *Make Your Freelance Business a Perpetual Feast*, *Complex Case Studies for Freelance Writers*, *\$200 (or More) and Hour? Yes, You Can Do It.*, and *Jam Session for Seasoned Freelancers*. Some common themes emerged among the sessions, including the definition of a successful freelance: having as much work as you want. Ideally, this work should pay well, be the type of work you most enjoy doing, and involve working with great clients. In these sessions, several speakers shared tips, advice, and stories from the freelance medical writing battlefield. Participation from the audience was welcomed; some of the sessions implemented audience response systems, and the “jam session” was an unstructured group discussion.

Nuggets of freelance medical writing wisdom shared during these sessions included:

- Invest in your professional freelance writing business: consult with lawyers, accountants, and insurance agents regarding your business structure; hire a graphic artist to design a logo to be used on your high-quality business cards, social media, website, and as your email signature; and hire a professional photographer to do your headshot
- Never stop marketing
- Never stop networking, both online (eg, LinkedIn and AMWA Engage) and in person
- Track your time and keep metrics so that you can better estimate projects
- Value yourself and your work; request competitive project fees, reasonable timelines, and never work at a discount – and be willing to turn down

projects that aren't quite right, with the faith that the right project will come soon

- Remind clients they are not buying your time but rather buying your value
- Be dependable, affable, flexible, and committed to each project
- Prophylactically manage scope creep by writing it into your contracts and renegotiate payment when it happens – don't let clients take advantage of you!
- Implement productivity and efficiency strategies, especially with respect to minimizing distractions and motivating around procrastination

As a 16-year successful freelance medical writer myself, these sessions reinforced what I'm doing right, reminded me of what I'm doing wrong (or not doing at all), and gave me plenty of new things to work on when I returned home. Above all, they reassured me that regardless of experience or type of writing, there is something for every medical writer at the AMWA Annual Conference!

GAIL FLORES, PhD, is the Principal Medical Writer at Encore Biomedical Communications. She has over 16 years experience developing and writing pharmaceutical sales training materials (including print, iPad, and e-learning modules, slide decks, companion pieces, workshop materials, and assessments), CME materials (including monographs, needs assessments, and interactive case studies), and peer-reviewed manuscripts and review articles published in top-tier journals such as the *Journal of Clinical Oncology*. A member of AMWA since 2005, she currently serves as the Membership Coordinator of the AMWA Pacific Southwest Chapter.



Twitter: @EncoreBioMed, @OncologyWriter
Facebook: <https://www.facebook.com/EncoreBiomed>

#AMWA2016 Tweets

Curated by **Ajay K Malik, PhD**

These days, every conference worth its salt ensures that attendees know its Twitter hashtag to create a buzz and give users another channel through which they can share their experiences and connect. At ASCO, the granddaddy of these clinical meetings, there are so many users posting so much content that it becomes a full-time job following the hashtag. Try searching #ASCO2016 hashtag on Twitter (<https://twitter.com/search?q=%23asco2016>).

AMWA members are a little different and medical writers seem to embody the “millennial generation”—recent trends suggest millennials are increasingly switching off their smartphones, closing their social media accounts, and reclaiming their time.¹ As Jonathan Marglis of *Financial Times* reports, 20-something-year-olds in the suburbs of London are attempting to disengage with all social media channels and even gravitating back to basic flip phones with only talk and text functions. Medical writers are also like that; most never got on the Twitter bandwagon; meanwhile, others keep it to the bare minimum as another channel on which to connect. Fortunately, a small group of AMWA members *did* live-tweet the Denver conference with hashtag #AMWA2016. And this gave us a window to share the excitement at the conference—enjoy a curated list of #AMWA2016 tweets below!

Kathy Boltz [@Kathybphd](#), Oct 3
Looking forward to #AMWA2016 this week!

Am Med Writers Assoc [@AmMedWriters](#), Oct 5
Watch out Denver! #AMWA2016 is here

Nicola Gillespie [@ngillespiedvm](#), Oct 5
Excited to be headed to Denver for #AMWA2016

Emily Gillespie [@ecg1324](#), Oct 6
[@rkhamisi](#) Great talk #AMWA2016! Jargon ex.: “hypergammaglobulinemia” used in first min of talk to lay audience. Great science, lost impact.

Roxanne Khamsi [@rkhamisi](#), Oct 7
Stating credentials really do make you more credible: Lori Alexander of [@Editorial_Rx](#) says: <http://www.tandfonline.com/doi/full/10.1080/10410236.2016.1172296> ... cc [@aldacenter](#) #AMWA2016

Larry Lynam [@scopedbylarry](#), Oct 7 Denver, CO
“Oh about numbers. Physicians and scientists love them. Lay audiences not so much” Lori Alexander reminding us- think visuals #AMWA2016

Dr Nicky Parry [@ParryMedWriting](#), Oct 7
How many people will be reviewing your project? “If more than 2 or 3, my rates go up,” says [@debragordon2012](#) (your work will increase) #AMWA2016

Dr Nicky Parry [@ParryMedWriting](#), Oct 7
“We had a bad experience w/another writer....” If you hear this, [@debragordon2012](#) recommends asking client what went wrong. #AMWA2016

Rochelle [@rochelleonearth](#) Oct 7
Aaron Bernstein on adoption of CORE to write CSRs: It’s a matter of the path being made by people walking on it. #AMWA2016

Adi Ferrara [@AdiFerrara](#), Oct 7
Excellent and packed (!) session on the new CORE Reference. #AMWA2016

Ruwaida Vakil, MS [@RuwaidaVakil](#), Oct 7
#AMWA2016 [@WriterLori](#) great tips, having a photo makes you 7x more likely to be found on LinkedIn

Nicola Gillespie [@ngillespiedvm](#), Oct 7
“Good writing is a treat for everyone.” Great tip from Kent Steinriede for writing and QC of Safety Narratives. #AMWA2016

Roxanne Khamsi [@rkhamisi](#), Oct 8
Here at #AMWA2016 [@KevinMD](#) says patients go online seeking *stories* about what it’s like to live w disease, not just stats CC [@aldacenter](#)

Lisa Carricaburu [@lcarricaburu](#), Oct 8
Health-care professionals need to stop seeing themselves as gatekeepers of medical info, and more as curators, says [@KevinMD](#). #AMWA2016

Erin L. Boyle [@erinLboyle](#), Oct 8
Risks exist for docs in using social media but “biggest risk of social media is not using it at all in health care” #AMWA2016 [@kevinmd](#)

Lisa Carricaburu [@lcarricaburu](#), Oct 8
[@kevinmd](#): When trying to combat anti-vaccine misinformation, stories resonate over data. Try to convince people on the margin. #AMWA2016

Kathy Boltz [@Kathybphd](#), Oct 8
Sans serif better to read from back of room. Ppt workshop, seated towards the back. #AMWA2016 #kelleen flagherty

DeeAnn Visk¹@DeeAnnVisk, Oct 8
One 15 minute phone call can eat up 1.5 hrs of day #AMWA2016

Larry Lynam¹@scopedbylarry, Oct 8 Denver, CO
It's important as a freelancer to make your client look good #AMWA2016 - @MedCaseWriter

Nicola Gillespie¹@ngillespiedvm, Oct 8
Stories resonate over data - @kevinmd #AMWA2016

Dr Nicky Parry¹@ParryMedWriting, Oct 8
"The moment at which we no longer think we need to learn, is the moment we need to give ourselves a reality check." ~ Flo Witte #AMWA2016

Dr Nicky Parry¹@ParryMedWriting, Oct 8
"I believe that everyone should have a mentor, whether formally or informally." ~ Flo Witte. #AMWA2016

Brian Bass¹@brianandcyndy, Oct 8
#AMWA2016 best medical writing & communication conference ever! So good seeing friends. Great knowledge exchange! Can't wait for #AMWA 2017

Notes:

- More millennials switch off social media. By Jonathan Margolis. Financial Times. Oct 09, 2016. <https://www.ft.com/content/5477680e-8ece-11e6-a72e-b428cb934b78>. Twitter: @TheFutureCritic.



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Chapter Dinner @ AMWA Conference

Photos by: **Donna Simcoe, MS, MS, MBA, CMPP**, Past President, AMWA Pacific Southwest Chapter



The 2016 Medical Writer's Toolbox Symposium: Something for Everyone

By Lynn Griffin, PhD, AMWA Pacific Southwest Chapter Member*

It was a sunny Saturday morning in September when about 50 members of AMWA Pacific Southwest Chapter got together at Amgen's vast campus in Thousand Oaks, CA, for the Medical Writer's Toolbox Symposium. Medical writers from all over Southern California came to learn about advanced Microsoft Word skills, Word templates, and document-sharing programs, and attend a special presentation about opportunities for medical writers in health economics and outcomes research (HEOR).

There was plenty of time between registration and the first presentation for coffee and networking. Nearly one-third of the attendees were new members or writers, including myself, but the conversations and coffee created a warm atmosphere. The presentations started on time and although the room was kept at a temperature just above freezing by an overactive air conditioner, the presentations got participants fired up about new tips, new software, and new opportunities for medical writers.

Tips, tricks, and templates in Microsoft Word

After a brief welcome and a few announcements from the chapter's past president, Donna Simcoe, Maggie Norris of Impax Laboratories gave the audience a tour of Microsoft Word tailored to the needs of the medical writer. The main message was "Customize, customize, customize." In an interactive presentation, Maggie showed how one can tailor the status bar, ribbons, toolbars, and panes to display only the tasks used most often. Maggie had some useful tips and tricks, such as, using the shift+F5 shortcut key to access the most recent document changes in reverse chronological order. She also discussed using templates to produce standardized documents, which can be especially helpful for ensuring compliance. An audience member shared that if you have questions and need a quick way to get an answer, tweeting to [@microsofthelp](#) is really effective.

A collaborative presentation on collaborative publication

Next up was a fun, collaborative presentation by Donna Simcoe of Simcoe Consultants and Ajay Malik of Intercept Pharmaceuticals. They delved

deep into document management, re-emphasizing the utility of templates in maintaining consistency and compliance for both regulatory and clinical documents. Many templates are commercially available, but some authors prefer to create templates specific to their needs. Following the theme of tools for writers, Ajay discussed various collaborative editing and document management software, such as, SharePoint, PleaseReview, and DxReview. All of these tools allow for real-time editing and tracking version history in a secure environment, addressing the needs of writers, publication managers, and senior management.

HEOR: Medical writing's next hot thing

Finally, Julie Gegner of Amgen presented a thorough review of an exciting and burgeoning area of medical writing: HEOR. In HEOR, scientists, economists, and writers communicate the *value* of an intervention so that payers can make informed decisions about drugs and devices. For example, when comparing two treatments, a payer must understand the difference in cost as well as the difference in the effectiveness. The data for this type of analysis could be as simple as comparing the survival curves of each treatment, taking into account quality-of-life measures. The optimal communication strategy involves identifying the audience, presenting basic models and statistics, and simplifying the language to engage the target audience, which may include healthcare professionals, patients, payers, governmental agencies, and those in industry, government, and academia.

A medical writer with expertise in HEOR typically develops dossiers that include a summary of the product (ie, a new medicine or device), the disease description, the clinical evidence for safety and efficacy, the economic value of the intervention, and a modeling and statistical report. These dossiers range from 50-500 pages and the HEOR writer uses document templates, reference managing software, and collaborative writing tools previously described in this symposium.

Julie's talk was followed by an energetic and lengthy Q&A demonstrating the high level of interest in HEOR. People asked about the experience and skills desired for an HEOR writer (mostly the same

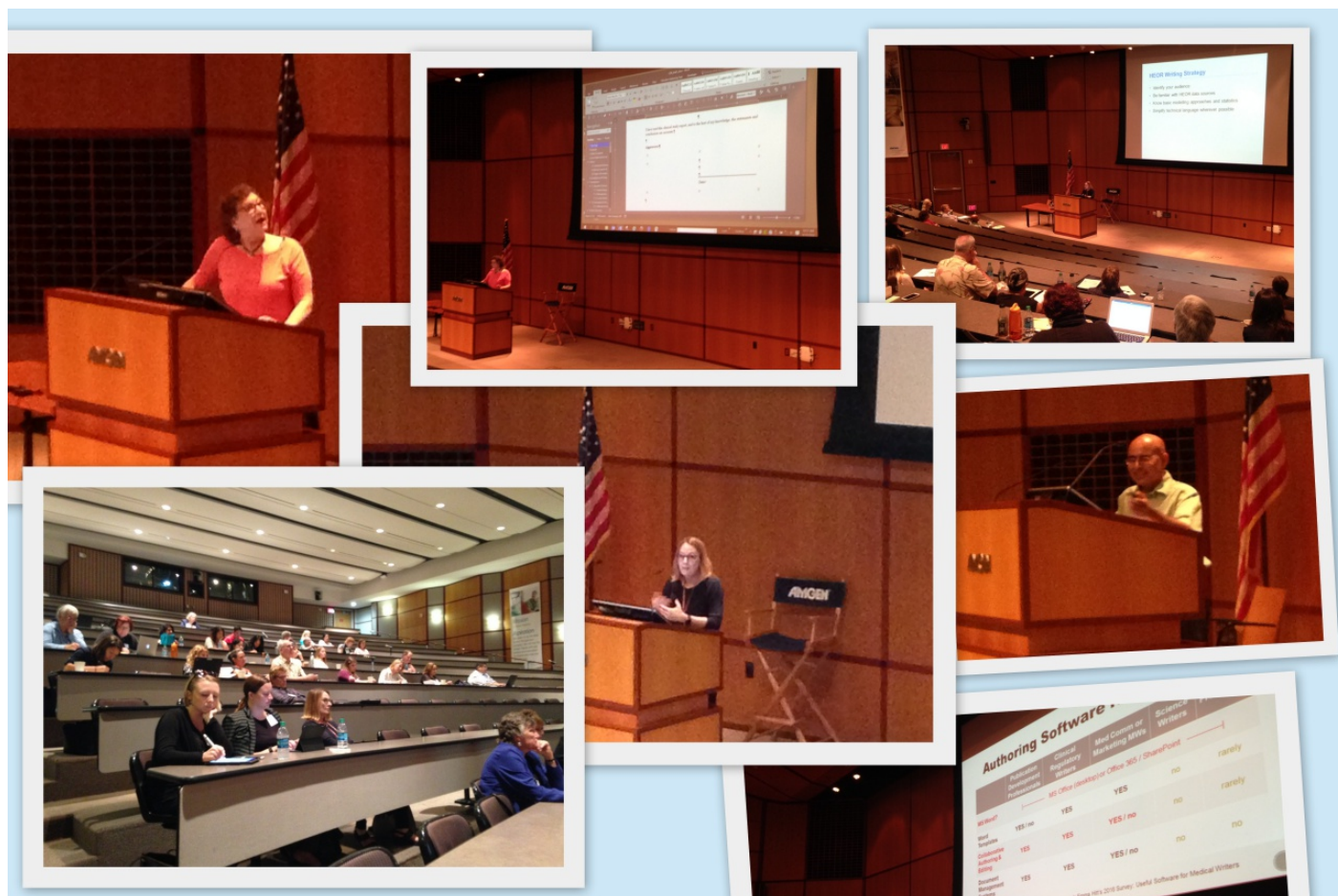
*At the time of drafting this article, Lynn was an independent writer and has since joined Amgen.

skills that we already have as medical writers), pay (very competitive) and demand (incredibly high), and the kinds of statistical analyses involved (mostly Markov and survival models). In all, HEOR is a promising area of growth for researchers and writers alike.

A great way to spend a Saturday

The AMWA Pacific Southwest Toolbox Symposium was a great way to spend a Saturday. The presenters had insights to share with all attendees regardless of their experience or specialty. We enjoyed the warm Southern California sun and Amgen's beautiful campus, an outdoor lunch, opportunities for networking with a diverse and friendly group of medical writers, and talks from the seasoned professionals of our chapter. The organizers did a wonderful job balancing time for sessions and time for networking. If you haven't yet attended one of these events, I recommend that you plan on coming to the next one. You won't regret it!

LYNN GRIFFIN, PhD, is a freelance medical writer and founder of Coalescence Communications. She loves data and information and is passionate about communicating complex ideas in ways that are accessible to novices as well as experts. Coalescence Communications serves the biomedical community by providing writing and editorial support on peer-reviewed manuscripts development, grant proposals, slide-decks, and continuing medical education. Lynn holds a PhD in Population Biology, Ecology, and Evolution from Emory University. During her graduate and postgraduate years, using genetic tools, she has studied symbiotic relationships between microbes and their insect hosts, as well as the evolution and speciation of wild animal populations. Most recently, she was a Howard Hughes Medical Institute Lecturer at University of California Santa Barbara in the Molecular, Cellular, and Developmental Biology Department. Learn more about Lynn at coalescencecommunications.weebly.com. She can be reached at coalescence.communications@gmail.com



Pictures by Donna Simcoe

AMA-zing Style — The AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc., Thousand Oaks, Calif.

Advertising, Journals and Ethics

Publishing scientific research is a highly profitable business for publishing houses. Commercial activities (eg, advertising, sponsorship, reprints, and e-prints) provide a major source of revenue for many scientific publishers. Using this revenue, journals can offset some of the costs of operations, production, and distribution; and can perhaps provide income for the owner. Thus, editors and readers often consider advertising an unfortunate necessity.

Editors have an ethical responsibility to ensure that the journal's integrity remains intact and that the information contained in the publication is valid and objective. This includes ensuring that advertising does not influence content.

Thus, editors should always have ultimate responsibility for all content published in their journals, including advertisements. The International Committee of Medical Journal Editors (ICMJE) recommends that editors "*have full and final authority for approving advertisements and enforcing advertising policy.*" According to the ICMJE, advertising must not influence editorial decisions. All editorial decisions must be based solely on the quality and suitability of the editorial content and should not be influenced by potential revenue, or loss of revenue, from advertising, sponsorship, sales of reprints/e-prints, or related commercial activities, or the influence of ad sales and marketing representatives.

Advertisements appear in print and online journals, e-mail alerts, other online information products and services, and other types of media (such as podcasts and blogs). In most cases, advertisers pay to place advertisements for their products and services in publications. Important considerations for editors and publishers are whether paid advertisements and sponsorship invite potential infringements on editorial independence and whether they represent important revenue opportunities for journals in increasingly competitive markets.

Scholarly editorial material is generally intended to be objective, whereas advertisements are generally intended to be preferential, selective, and persuasive. Problems arise when the means to achieve the common goal of influencing behavior fall outside expected norms or violate specific regulations and standards. In many countries, advertisers must meet specific criteria established by national regulatory agencies. For example, drug ads are required to follow the regulations of the Food and Drug Administration (FDA) in the United States, and the Association of the British

Pharmaceutical Industry (ABPI) in the United Kingdom.

Advertising-to-Editorial Content Ratio. The ICMJE recommends that journals not be dominated by advertising and that they avoid publishing advertisements from only 1 or 2 advertisers; otherwise readers may perceive that the journal is sponsored by 1 or 2 advertisers and that these advertisers have influenced the editor and the editorial content.

Advertising Interspersion. Placing advertisements between articles and interleaving them within articles may attract advertisers, but such practices may also diminish the perceived credibility of the publication—especially if the ads create difficulty for the reader in reading or finding editorial content. For scholarly biomedical journals, ads should not be interleaved within a scientific or clinical article in print or online.

Advertising-Editorial Juxtaposition (Adjacency). Advertisers may request placement of their ads next to related editorial content to help promote their products. Although common in consumer publishing, this practice is discouraged by the ICMJE. Ad adjacency, like ad interspersion, may be an impediment to readers and may diminish the perceived integrity of a scholarly publication.

Editorial Calendars. Providing advertising sales representatives with editorial calendars that include specific content scheduled for upcoming issues invites pressure for advertising-editorial adjacency and other attempts from industry to interfere with editorial decisions. The ICMJE states that advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Sponsored Supplements. Sponsored supplements are collections of articles, usually on a single topic, and are published as an extra edition or a separate section of a journal, often after a meeting or symposium. Supplements are often sponsored by a single company. Because of the perceived promotional and biased quality of such industry-sponsored supplements, JAMA and the Archives Journals will not publish them. In addition, the US National Library of Medicine will often not index articles in sponsored supplements.

See pages 276-290 in the AMA Manual of Style 10th edition for additional information.

Acknowledgement: Thanks are due to Ajay Malik PhD for discussions

PubsHub: Painless Publication Planning

By Lynn Griffin, PhD, AMWA Pacific Southwest Chapter Member*

With the completion of a clinical trial and data analysis, two activities are set in motion at the trial sponsor company: (1) preparation of regulatory filing documents that includes clinical study reports, and (2) medical disclosure documents. Medical disclosure documents generally take the form of peer-reviewed publications, conference abstracts, and posters, and are key to dissemination of clinical study data to the public, patients, and physicians.

The preparation and publication of medical disclosure documents must follow established guidelines, regulations and best practices, such as good publication practice (GPP3) and International Committee of Medical Journal Editors (ICMJE) guidelines, and collect data to facilitate Sunshine Act reporting. These tasks are handled by publication planners and medical writers.

Publication Management

Publications management is complex and requires attention to lots of details. For example, a publication planner/medical writer will need to manage the entire process, coordinate reviews by co-authors and publication team, archive document versions as proof of author contributions, coordinate authors' commenting process, and manage timelines.

Without dedicated software in place, the manuscripts are often circulated by email with comments returned individually to the medical writer (aka the writing lead) or a corresponding author. The writing lead is then responsible for collecting and collating the comments, revising the document, and possibly sending the draft out for another round of revisions. The process is highly inefficient, laborious, error-prone, and leaves a complicated audit trail.

PubsHub

PubsHub is a cloud-based publication management system that can increase efficiency in publication management process and improve compliance. The program has an intuitive interface that allows project collaborators to access the most recent version of a document, review, and make edits. The software also tracks and timestamps comments and edits, and maintains all document versions. An audit trail can be easily generated to demonstrate author contribution (a requirement to be an author under ICMJE guidelines), leaving more time for publication planner/medical writer to focus on getting the manuscript submitted for publication in a timely manner, rather than the administrative tasks.

Multitasking and Project Planning: What makes PubsHub especially useful for the medical writer is

the ability to simultaneously manage diverse project types (abstracts, manuscripts, slides, posters, CSRs, dossiers, etc.) and to manage projects in different therapeutic areas. Projects can be visualized in a short-term or longer-term calendar view. The calendar can display and manage multi-year projects, which can be helpful in long-term coordination of clinical trials and publication planning. The software's landing page allows the medical writer to view a list of pending tasks and highlights upcoming deadlines. Metrics and milestones can be tracked for projects across products, devices, and therapeutic areas, making PubsHub a sort of one-stop, tracking software for multiple projects.

Journals and Congresses Search Tool: PubsHub also offers the exciting Journals and Congresses product that allows you to search, filter, sort, and compare journals in a particular therapeutic area by their impact factor, average time from submission to acceptance, and rejection rate. There is also a direct link to the author guidelines and editors of each journal in the database. Congress information includes the size (attendance) of the congress, date/location of the next meeting, and, importantly, the abstract submission requirements and deadline. You can also set up alerts to notify you of submission deadlines. These features streamline the process of selection and submission to the most appropriate congress venue and are helpful for those striving to coordinate simultaneous publication of simultaneous publication in multiple therapeutic areas.

Overall, publication planners strive for a process that is secure, compliant, and less prone to error. PubsHub is one tool that organizes and streamlines the publication process. If you are working in-house, you may already be familiar with PubsHub or similar software (such as DataVision or PubSTRAT). If you have not yet adopted a publication planning software to manage the publication process, now is the time to try out. Although, there is no free trial version of PubsHub offered, medical writers can obtain a free trial of PubsHub's Journals and Congresses module at their website (<http://jandc.pubshub.com/Users/Register>). Any questions or inquiries regarding PubsHub can be directed to Jessica Poarch, the PubsHub client services manager (jp@PubsHub.com).

ACKNOWLEDGMENT

The author thanks Ajay Malik, PhD, for helpful comments and editing of this report.

*At the time of drafting this article, Lynn was an independent writer and has since joined Amgen.

Rules of Engagement on Social Media for Biopharma and Medical Writers

By Ajay K Malik, PhD, Editor, Postscripts

Social media, including Twitter, Facebook and LinkedIn, are not really “media” in the traditional sense of print, radio or television, but are platforms for *interaction and engagement*.¹ Thus, using these social media platforms requires special consideration by the pharmaceutical and medical device industry if they choose to engage the public, patients, healthcare providers, policy makers, and other stakeholders through this medium.

Twitter was established 10 years ago in June 2006, while Facebook has been around for 12 years (since 2004), and LinkedIn is even older (was launched in 2002.) Together, these platforms command the attention of nearly half a billion (Twitter or LinkedIn) to over a billion users (Facebook). So, it is no surprise that the industry considers these platforms as another channel to engage patients and healthcare providers.

Today, a large number of biotech and pharmaceutical companies already have a presence on three of the most common social media outlets that include Twitter, Facebook and LinkedIn. Since 2013, the average number of tweets posted on these pharmaceutical industry accounts has gone up by 530%, and the number of people following their accounts has also steadily increased, though the number of followers does not prove *engagement*.²

Rules for the Industry

The industry has a roadmap for routine social media use, as well as for responding to misinformation posted on these forums, in the form of draft guidance published by the Food and Drug Administration (FDA) in June 2014.^{3,4}

The key rules for engagement on social media for the industry are:

1. Balance risk and benefit information regardless of space limitations. Information regarding side-effects and black-box warning may be provided via link to a product information website, and
2. Use both generic and tradenames in the tweet or post.

The focus is on transparency and balance—balance with respect to the safety and efficacy parameters. Companies usually have dedicated employees responsible for posting information on the company's official social media accounts, and someone is often designated as “social media compliance officer.”

Medical Writers as Employees

Medical writers may have their personal social media accounts, and they have the right to express their personal views. However, posting of any company-related information on these accounts is governed by the standard operating procedures and internal company guidelines, and of course, common sense.

Some of the Do's and Don'ts include not tweeting or posting about:

- Company's product (drug or device),
- Nonpublic or confidential company information,
- Trade secrets,
- Patient or personal privacy information, or
- Medical advice.

Furthermore, even linking to company's press releases in a tweet or post may sometimes be considered as promoting unbalanced information, ie, promoting drug's benefit over its safety profile. Companies often have their product-specific website with balanced information that the public can find using search engines or by navigating from a company's homepage. Thus, all conversations should be directed to the product-specific website.

As user of social media while being an employee, a medical writer also has the responsibility of forwarding any adverse event report they encounter online, to the company's pharmacovigilance department for proper investigation and reporting.

Contract or Freelance Medical Writers

Contract or freelance medical writers may not be privy to a company's confidential information, however, it is still a best practice to follow the do's and don'ts as a full-time employee of a company would, and not become a headache for the company's social media compliance officer!

Where can I get more information?

FDA's definition of social media is broad: “Social media are web or mobile based third-party platforms that facilitate interaction and engagement among individuals in a network or virtual community. Social media offers a participatory environment and includes user-generated content such as videos, photos, videos, microblogs, blogs, and wikis.”⁵ Thus, the FDA guidance extends beyond Twitter, Facebook and LinkedIn.

The links to the most recent Federal Register notices and updates to Guidelines are available at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm397791.htm>.

Sources:

1. Just What is Social Media, Exactly? By Mark 'Rizzn' Hopkins. Mashable. 2008, Nov 18. Available at <http://mashable.com/2008/11/18/social-media-defined/>
2. Pharma, The FDA And Social Media. By Joanna Belbey. Forbes. 2016, May 15. Available at <http://www.forbes.com/sites/joannabelbey/2016/05/15/pharma-the-fda-and-social-media/>
3. Guidance for Industry. Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance). FDA. June 2014. Available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf>
4. Guidance for Industry. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Draft Guidance). FDA. June 2014. Available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401079.pdf>
5. FDA Social Medical Policy. Nov 2015. Available at <http://www.fda.gov/aboutfda/aboutthiswebsite/websitepolicies/ucm472483.htm>

Interesting birds of prey, including black bears and beavers spotted by Megan Garlapow on her way to Denver from Arizona!

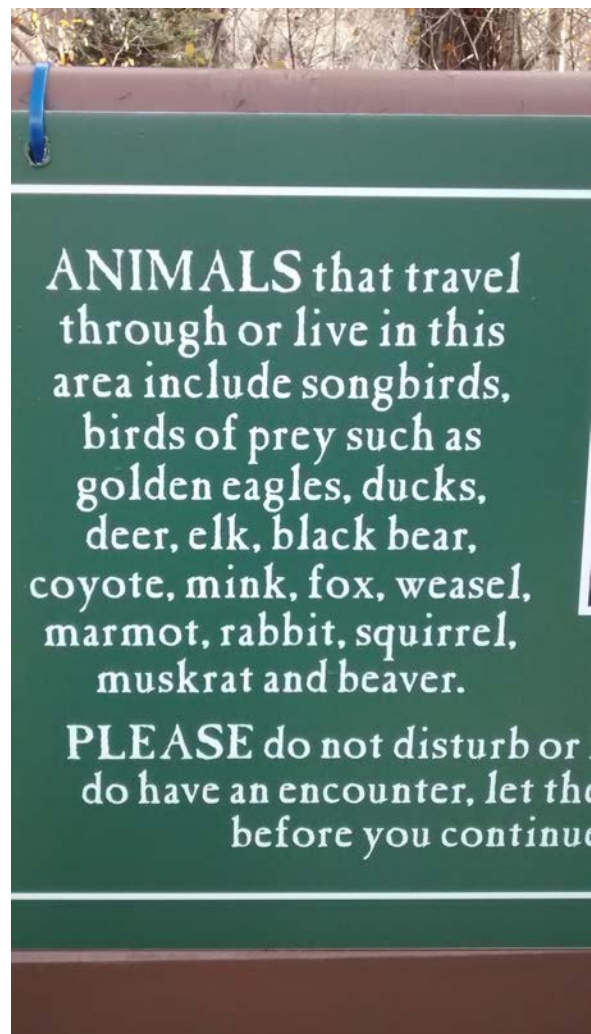


Photo provided by Megan Garlapow.

Optimizing Sponsor/CRO Relationships to Streamline Clinical Studies

By Roberta Alexander, PharmD, PhD, Exagen Diagnostics, Inc, Vista, CA

ClinPulse by PRC Clinical

ClinPulse is an expert panel and networking event series organized by PRC Clinical. Most of the ClinPulse events are held in the San Francisco area, as PRC is headquartered in San Bruno, CA, but on September 28, 2016, PRC came down to SoCal. The San Diego event took place at the Sanford Institute for Regenerative Medicine, and was a great networking and learning opportunity. Panelists were Mary Syto from Receptos, Teri Hicks from Statistics and Data Corporation (SDC), and Sue Dowden from PRC Clinical. All the panelists have extensive experience in clinical research. Teri's perspective focused mainly on data management and biostatistics, while Sue's experience lies mainly in clinical operations. The discussion was moderated by Jennifer Reichuber from Altani Associates.

What are the tips and tricks for a successful interaction between CRO and Sponsor?

Not surprisingly, the most important aspect of any good relationship is clear communication and transparency. A face-to-face kickoff meeting is very important, not only to discuss the project, the expectations, and the roles and responsibilities of the team members, but also to build personal relationships. Personal interaction facilitates trust and understanding. A social event the night before the kickoff meeting is useful in building camaraderie. The kickoff meeting is a good opportunity to lay out the expectations: as a sponsor, don't assume that the CRO's clinical operation team knows the terms

of the contract. Understanding who the team members are, their experience, and their role in the project, helps in building a successful team. Everybody at the kickoff meeting should introduce themselves by briefly describing their background, expertise, and role in the project. Weekly meetings are a good strategy to touch base. Often, it's not necessary to set an agenda, because what is most important is just to talk and share thoughts. These weekly meetings are especially productive if they are conducted one-on-one with your counterpart in the project: too many people talking simultaneously on the telephone could make effective communication difficult.

Understanding the communication style of your partner is an important element of successful communication. People who prefer to email because they want to keep a record of everything may get frustrated if they don't receive a response quickly. Instead of getting frustrated, it may be more productive for these people to simply pick up the telephone.

In terms of transparency, the CRO may find it useful to know that the sponsor has a board meeting or an investor meeting coming up; they will better understand the needs of the company. After all, both sponsor and CRO have the common goal of delivering a successful clinical program and, as such, both should subscribe to the following sentiment, "It's not my team or your team, but our team!" In addition, the CRO often brings valuable



From the left: Sue Dowden, Teri Hicks, Mary Syto, and Jennifer Reichuber.

expertise; sponsors should not view the CRO as somebody who works for them and has to do things their way, but, rather, as a partner who could contribute valuable insight.

The CRO needs to share the enthusiasm of the sponsor. While this may seem obvious, it's important that the sponsor's representative is passionate about the product and study protocol, and communicates this enthusiasm during protocol training.

A company may work with multiple CROs during the same project, and different vendors may need to interact with one another. It may be useful if the CROs interact directly. Of course, the sponsor needs to agree to this type of direct communication; however, it could be beneficial for all the parties involved.

How do you pick the CRO that best fits your needs?

A large CRO may not necessarily make sense for a big study. Although it may seem easier to work with one CRO and one contract, it may not always be the best solution. Small CROs are often functional CROs. Although they have experience in a particular area, but not another, this should not be viewed as a weakness. For example, SDC focuses on data management, and it partners often with PRC Clinical for what clinical operations are concerned.

What are the warning signs that something is going wrong?

Lack of engagement, lack of communication, and not meeting deadlines are potential red flags. On the other hand, some difficulties in the study may simply

be due to a difficult therapeutic area, or strict inclusion and exclusion criteria that make enrollment slow. In any case, make sure everybody is clear about deadlines. Deadlines are not necessarily dates, but how many months are needed to accomplish a certain deliverable.

Can you fire the CRO?

Yes, you can, but be sure you understand the consequences. For example, if the sponsor owns the electronic data capture (EDC) tools, the second CRO can jump in relatively easily. On the other hand, if you are close to data lock, it may just be easier and cheaper to stay the course. Keep in mind that moving data from one EDC system to another may not be straightforward, and you may have to maintain both EDCs for regulatory purposes.

The attendees enjoyed the networking and actively participated in the discussion. We look forward to the next ClinPulse event in San Diego!

ROBERTA VEZZA ALEXANDER, PharmD, PhD, is the Associate Director of Clinical Research and Medical Affairs at Exagen Diagnostics, Inc. where she designs and oversees the company's clinical studies. Dr. Alexander transitioned recently in the diagnostics space, as she spent most of her career in drug discovery working in the pharmaceutical industry. She holds a PharmD and a PhD from the University of Perugia, Italy, and came to the USA for a postdoctoral fellowship at the University of Pennsylvania. She has been living in San Diego with her husband since leaving Philadelphia, and loves to walk on the beautiful beaches of Southern California. She can be reached via LinkedIn: www.linkedin.com/in/robertavalexander/



Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**

Employment Coordinator, AMWA Pacific Southwest Chapter

Director, Medical Writer

Avanir Pharmaceuticals, Inc., Aliso Viejo, CA

<http://job-openings.monster.com/monster/e90408f5-3251-4ed8-a03e-267de7bf5c5a?mescoId=1100049001001&jobPosition=8>

Scientific Writer

City of Hope, Duarte, CA

<http://job-openings.monster.com/monster/3e6c426d-a73a-4a6a-a3b1-cb07e86ceb08?mescoId=2700440001001&jobPosition=21#>

Medical Writer - Pharmaceutical

Brandkarma, Irvine, CA

<http://careers.brandkarma.org/medical-writer.html>

Associate Specialist, Technical Writing - Critical Care

Edwards Lifesciences, Irvine, CA

https://edwards.taleo.net/careersection/edwards_external_cs/jobdetail.ftl?job=009030&src=JB-10046

Medical Writer

Glidewell Laboratories, Irvine, CA

<http://www.indeed.com/cmp/GLIDEWELL-LABORATORIES/jobs/Medical-Writer-eb84dda1a216da8f?q=medical+writer>

Medical Writer

Medtronic, Irvine, CA

<http://jobs.medtronic.com/jobs/medical-writer-18555?src=JB-10288>

Principal Scientist - Medical Writing

Cardinal Health, La Jolla, CA

<http://job-openings.monster.com/monster/36728709-017c-4e95-ae79-fd5e5d19c778?mescoId=2700440001001&jobPosition=24>

Associate Director, Medical Writing (Publications)

Intercept Pharmaceuticals, La Jolla, CA

<https://interceptpharma.com/career/associate-director-director-medical-writing-publications/>

Senior Medical Writer

Intercept Pharmaceuticals, La Jolla, CA

<https://interceptpharma.com/career/sr-medical-writer/>

Director, Medical Writing

Atara Biotherapeutics, Los Angeles, CA

<http://app.jobvite.com/CompanyJobs/Careers.aspx?k=Job&c=qk0aVfw9&j=o7CS1fwm&s=Indeed>

Manager of Scientific Publications

Quest Diagnostics Incorporated, San Clemente, CA

<http://job-openings.monster.com/monster/b87fa9b2-4a15-47cd-8dc7-257831b6b5d1?mescoId=1100048001001&jobPosition=2#>

Director, Medical Writing

Acadia Pharmaceuticals Inc., San Diego, CA

<http://job-openings.monster.com/monster/dabeaf8e-2f59-447b-aad5-bdf13097b757?mescoId=1100049001001&jobPosition=4>

Principal Medical Writer

Halozyne, San Diego, CA

<http://job-openings.monster.com/monster/81be3c83-19a0-420b-9654-ef4838138418?mescoId=2700440001001&jobPosition=23#>

Associate Director/Director, Medical Writing (Publications)

Intercept Pharmaceuticals, San Diego, CA

<http://job-openings.monster.com/monster/531f1663-11ee-41ab-8fe6-ad20ff7d1c14?mescoId=1100049001001&jobPosition=5>

Science / Medical Proofreader (Marketing)

International Programming & Systems Inc., San Diego, CA

https://ipsamerica.com/Jobs/Info.aspx?id=4165i&id2=6&utm_source=Indeed&utm_medium=organic&utm_campaign=Indeed

Medical Writer

Meridius Health Communications, San Diego, CA

<http://www.indeed.com/cmp/Meridius-Health-Communications/jobs/Medical-Writer-bf5bca05280b59e0?q=medical+writer>

Technical Editor (Contractor)

MLS Technologies, Inc, San Diego, CA

http://search4.smartsearchonline.com/receng/jobs/jobdetails.asp?current_page=2&city=&location=&job_type=&emp_status=&country=&k1=&k2=&k3=&k4=&k5=&k6=&k7=&k8=&salary_min=&co_num=&apply=yes&job_number=905&sourcename=Indeed

Medical Writer (Cardiology)

ScienceMedia, San Diego, CA

<http://www.indeed.com/cmp/ScienceMedia/jobs/Medical-Writer-296ff39bd1412291?q=medical+writer>

Medical Writer (Oncology)

ScienceMedia, San Diego, CA

<http://www.indeed.com/cmp/ScienceMedia/jobs/Medical-Writer-c26cec8071bd971d?q=medical+writer>

Medical Writer

Therapeutics, Inc., San Diego, CA

<http://www.biospace.com/jobs/job-listing/medical-writer-362260>

Manager Medical Writing, Clinical Research

Abbott Laboratories, Santa Ana, CA

<https://www.jobs.abbott/job/-/13/3161011?apstr=&sourceid=Indeed&source=Indeed&ss=paid>

Regulatory Writing Manager

Amgen, Inc, Thousand Oaks, CA

<http://www.biospace.com/jobs/job-listing/regulatory-writing-manager-362110>

Senior Medical Writer - Remote

MMS Holdings Inc, Thousand Oaks, CA

<http://mmsholdingsinc.applytojob.com/apply/0c3b061d7e5e706c6a615c595a55030a50756f462b1124143b094219714e025f47610b/Senior-Medical-Writer-Remote?source=INDE&sid=fTdBlnAZZRnmkl63dF0tjFoXnBuJ7wUnp7Y>

Senior Medical Writer, Regulatory Writing (Home Based)

INC, no location stated

<https://incresearch.taleo.net/careersection/ex/jobdetail.ftl?job=16004888&src=JB-10480>

Principal Medical Writer (Remote)

PRA Health Sciences, No location stated

<https://uscareers-prahs.icims.com/jobs/37267/principal-medical-writer/job?mode=job&iis=Indeed&iisn=Indeed.com&mobile=false&width=1263&height=500&bga=true&needsRedirect=false&jan1offset=-480&jun1offset=-420>

Medical Writer (Oncology)

Real Life Sciences, San Diego, CA

Contact b.custeau@realstaffing.com

If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

Upcoming Chapter Events

Nov 04 Nov 09 Dec 01

AMWA Pacific Southwest Chapter Lunch (Monthly) Teleconference

Occurs First Friday of the month, 12:00-1:00 PM Pacific time

Hosted by Donna Simcoe, Past President of the Chapter

Dial in number: 706-913-1155

Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)

Free. Open to members and non-members.

Next Meeting on **Friday, November 4th**: Year-end topics.

Wednesday, November 9 2016, 5:30-8:30 PM

Joint meeting between San Diego STC and AMWA Pacific Southwest Chapter

"Writing and Editing for Biotech, Pharmaceutical, and Medical Device Companies"

Speakers: Nancy Rhoads, who will be speaking about technical writing for medical devices and Ajay Malik, PhD, who will talk about medical writing.

Place: Hera Hub, 4010 Sorrento Valley Blvd #400, San Diego, CA 92121

Register at <https://www.eventbrite.com/e/tech-writing-and-the-american-medical-writers-association-tickets-28271326298?ref=ebtn>

SAVE THE DATE:

- **December 1, 2016**: Webinar: Mentor and mentee training for participants in PacSW AMWA Mentorship Program
- **February 2017**: Jane Rollins will talk about her experience publishing her book on healthcare information for patients



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2017 CSE Annual Meeting

May 20-23, 2017
San Diego, California

What's Happening at AMWA National

CORE Reference

AMWA partnered with EMWA to create the CORE Reference, a user manual to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content. <http://www.amwa.org/core>

AMWA Online Learning

Our catalog of online learning activities continues to grow with more coming this month! Interactive, self-guided online learning includes:

- The Role of the Regulatory Writer
- Drug Development Essentials: Regulatory Documents for Developing Clinical Studies and Reporting Clinical Data
- Drug Development Essentials: Regulatory Documents for Getting a Drug to Market and Monitoring Safety
- Ten Characteristics of Effective Tables and Graphs
- Harness the Power of EndNote: Manage Your Library's Data

Regulatory Writing Overview package – Jump-start a career in regulatory writing with this three-part online learning activity. Save over 15% by purchasing all three activities as a package. Learn more at www.amwa.org/regulatory123.

A Career in Medical Communication: Steps to Success – Designed to answer the most frequently asked questions about becoming a medical writer, this online learning activity will explore what medical communicators do, where they work, and the variety of documents they produce. Explore further at www.amwa.org/careersteps.

Find these activities, archived recordings of AMWA Live Webinars, Pocket Trainings, and more in AMWA Online Learning at www.amwa.org/online_learning.

Essential Skills package

Purchase all 7 Self-Study Workbooks and earn the AMWA Essential Skills certificate at your own pace. Certificate enrollment is included. http://www.amwa.org/es_express

UPCOMING AMWA WEBINARS:

Tilt the Scales in Your Favor

November 17, 2016 | 1:00 PM -2:00 PM ET

Visit the AMWA Event Calendar (http://www.amwa.org/calendar_list.asp) for a full list of upcoming events, and registration details. Most webinars are \$55 for members and \$95 for non-members.



AMWA EDUCATION
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AMWA Pacific Southwest Chapter Warmly Welcomes Our New Members

Bradford Nguyen – San Diego

Krithi Bindal – San Diego

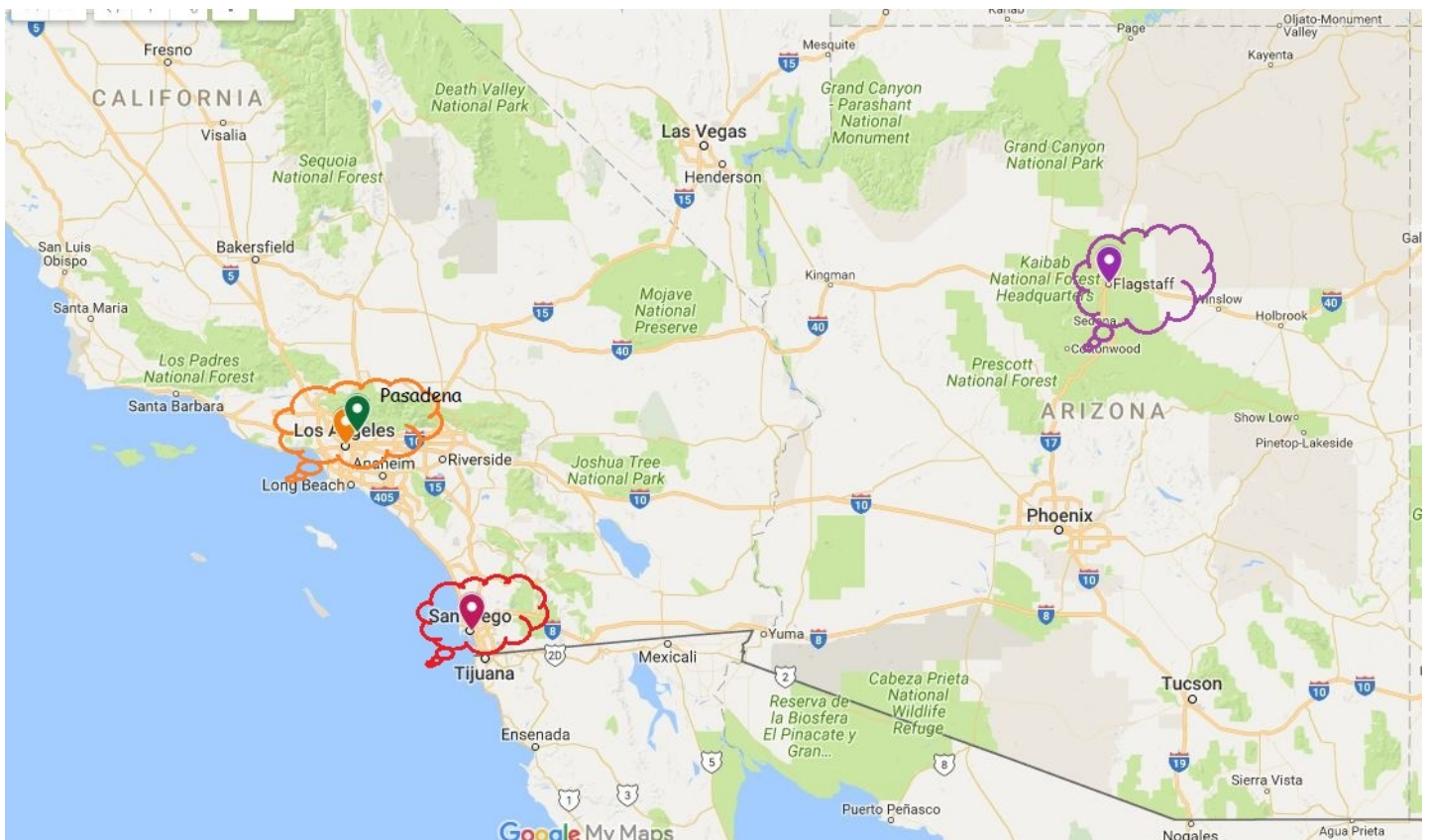
Maksim Khotimchenko – San Diego

Nihal Sarikaya – Flagstaff, AZ

Randee Bertussi – San Diego

Subramanian Krishnan – Pasadena

Zlatka Stojanova – Los Angeles



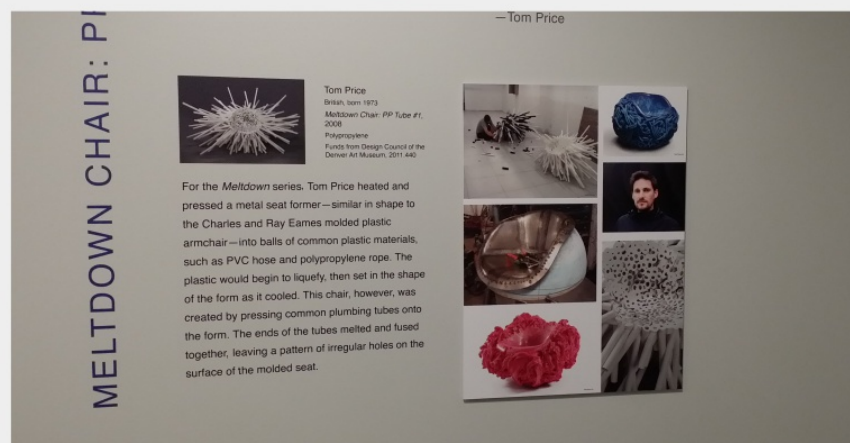
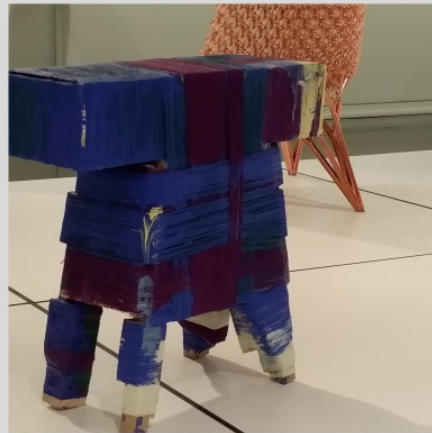
List courtesy of Gail Flores, PhD, AMWA Pacific Southwest Chapter membership coordinator.

Email: member-coordinator@amwa-pacsw.org

Unseated: Contemporary Chairs Reimagined Exhibit at the Denver Art Museum

By Susan Vintilla-Friedman, MWC, President, AMWA Pacific Southwest Chapter

The Denver Art Museum was a short 10-minute walk from the 2016 AMWA Medical Writing and Communication Conference in October, and it included this exhibit of “artist’s renditions” of chairs and concepts about chairs. Probably none of these chairs would be recommended for ergonomics, but they were all more entertaining than what we find in our own offices. The beautiful Denver Art Museum also has one of the most impressive collections of Western and Native American art in the US, and is highly recommended for your next trip to Denver.



Pictures by Susan Vintilla-Friedman. Collage by Ajay Malik